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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/801,089	03/08/2001	David R. Phillips	MPI95-0151RCPA1DVIM	7657

7590 03/29/2004

INTELLECTUAL PROPERTY GROUP
MILLENNIUM PHARMACEUTICALS, INC
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CAMBRIDGE, MA 02139

EXAMINER

EWOLDT, GERALD R

ART UNIT PAPER NUMBER

1644

DATE MAILED: 03/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/801,089	PHILLIPS ET AL.	
	Examiner	Art Unit	
	G. R. Ewoldt, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 September 2003 and 05 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-23 and 30-40 is/are pending in the application.
- 4a) Of the above claim(s) 35-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 21-23 and 30-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's election without traverse of the species: carcinoma cell, filed 9/08/03, is acknowledged.
2. Claims 35-40 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected species.

Claims 21-23 and 30-34 are being acted upon.

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 21-23 and 30-34 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted step comprises some sort of determination regarding how the phosphorylation state of an integrin is connected to signaling. The claims are drawn to a method of determining signaling. The actual action of the claims is to measure phosphorylation. Accordingly, the claims require some sort of action linking the measuring of phosphorylation to signaling.

5. Claims 21-23 and 30-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, specifically the term "signaling" in Claim 21 is vague and indefinite as it is undefined. While it is likely Applicant intends the term to encompass the outside-in and inside-out signal transduction described in the specification, it is unclear what other types of signaling would be encompassed by the claims. Accordingly, the metes and bounds of the claimed invention cannot be determined.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 22-23 and 30-34 are rejected under 35 U.S.C. § 112, first paragraph, as the specification does not contain a written description of the claimed invention, in that the disclosure does not reasonably convey to one skilled in the relevant art that the inventor(s) had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

The specification and the claims as originally filed do not provide support for the invention as now claimed, specifically, the generic method comprising the steps of Claim 22 and the limitations of Claims 23 and 30-34.

Applicant argues that support for the claim can be found at pages 37-38, 43, and 28-32. A review of the specification shows that at pages 37-38 the specification discloses only a method for determining the phosphorylation of tyrosines as a measure for metastatic potential, page 43 discloses only a method involving the tyrosine phosphorylation of GPIIb-IIIa in platelets, and pages 28-32 disclose no methods at all but rather a discussion of the various integrin β subunits. These specific disclosures are insufficient support for the generic method of the claims.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 21-23 and 30-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huang, M.-M., et al. (1993, IDS) in view of Agrez, M., et al. (1994).

Huang, M.-M., et al. teaches a method of identifying signaling mediated by an integrin β comprising analyzing integrin β -containing cell extracts with an anti-phosphotyrosine antibody employing an SDS-containing buffer (see particularly page 474, last paragraph).

The reference teaching differs from the claimed invention only in that it does not teach the analysis of signaling in carcinoma cells.

Agrez, M., et al. teaches that signaling through an integrin β subunit is involved in the proliferation of carcinoma cells (see particularly Results, page 549).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to perform a method of identifying signaling mediated by an integrin β comprising analyzing integrin β -containing cell extracts with an anti-phosphotyrosine antibody employing an SDS-containing buffer, as taught by Huang, M.-M., et al., employing a carcinoma cell as the cell to be analyzed. One of ordinary skill in the art at the time the invention was made would have been motivated to analyze integrin signaling in a carcinoma cell given the teachings of Agrez, M., et al. that signaling through an integrin β subunit is involved in the proliferation of carcinoma cells. Note that dependent Claims 31 and 32 recite the use of electrophoresis as a method of separating the cell extract. Various methods of cell component separation, e.g., gel electrophoresis or column chromatography, were well-known in the art at the time of the invention. The choice of any particular method of cell extract separation would have comprised only routine optimization of the claimed method and would have been well within the purview of one of ordinary skill in the art at the time of the invention.

10. No claim is allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Gerald Ewoldt whose telephone number is (571) 272-0843. The examiner can normally be reached Monday through Thursday from 7:30 am to 5:30 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841.

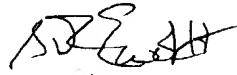
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Art Unit 1644

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Inquiries of a general nature may also be directed to the
Technology Center 1600 Receptionist at (571) 272-1600.

G.R. Ewoldt, Ph.D.
Primary Examiner
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3/25/04
G.R. EWOLDT, PH.D.
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